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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,866	05/16/2005	Kenneth J. Ruchala	013869-9005-01	4683

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EXAMINER	
KISH, JAMES M	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,866	RUCHALA ET AL.	
	Examiner	Art Unit	
	JAMES KISH	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed March 2, 2009 have been fully considered but they are not persuasive.

Firstly, the Examiner notes that the Applicant has canceled originally examined claims 14-26 and has added new claims 27-57.

Secondly, the Examiner respectfully disagrees with the Applicant's argument that Miller fails to teach "(a) obtaining at least one image from the patient in substantially a treatment position, the image being adequate for dose calculations; and (b) adjusting how the dose is received by the patient." Regarding part (a), the Examiner points the Applicant to column 9, lines 3-8 and column 10, lines 14-22, which were both previously cited in the previous Office Action. These portions describe imaging a patient to create a reference radiograph and obtaining CT scan data from the patient. "The CT scan has all the tissue densities in very fine detail. These tissue densities are readily digitized, thereby providing a map of the tissue densities, in three dimensional form..." This also is provided as a rebuttal to the Applicant's arguments throughout the remainder of the *Remarks* that "the radiograph image acquired by the x-ray source while the patient is positioned in the mean delivery system are only two-dimensional. It is known in the art that two-dimensional x-ray images do not include dose information. Therefore, the radiograph acquired while the patient is positioned in the beam delivery system is not suitable for dose calculation." With further regard to this argument, the Applicant's assertion that "it is known in the art that two-dimensional x-ray images do not include

dose information" is an opinion unsubstantiated by any factual evidence. A two-dimensional image is "adequate for dose calculations" within the plane of the image and this is specifically taught in the following Frohlich reference.

Regarding part (b) as previously stated, the Examiner cites column 15, lines 50-61 which was previously cited in the previous Office Action as teaching, "If the two views are not substantially the same, then that is an indication that something is not right. For example, the table position may have not been properly set, or the agulation angle may not be correct. If an irreconcilable discrepancy exists... then the whole process, including gathering new CT scan data and formulating a new treatment plan, will likely have to be repeated." Therefore, Miller teaches "adjusting how the dose is received by the patient."

Claim Objections

Claims 28-33, 37-39 and 55-57 are objected to because of the following informalities:

Claim 28 is objected to because it is unclear whether "a planned dose distribution" as stated in claim 28 is different from "a planned dose distribution" as stated at line 7 of claim 27. Furthermore, it is unclear how claim 28 relates to claim 27 because claim 27 states that "the treatment plan includ[es] a planned dose distribution" while claim 28 states "generating a planned dose distribution for the patient based on the treatment plan."

Claims 29-33 are objected to because each of these claims refers to "a dose distribution" or "the dose distribution." With respect to "a dose distribution," it is unclear whether this is the previously claimed "planned dose distribution" or a new dose distribution. With respect to "the dose distribution," this lacks antecedent basis because the previously claimed subject matter is a "planned dose distribution."

Claim 30 is objected to because it is unclear how "modifying the treatment plan and the dose distribution" is different from "adjusting how the dose is received by the patient" as claimed in claim 27.

Claim 32 is objected to because "the at least one image acquired from the patient at the time of treatment delivery" lacks antecedent basis because, at least, there is no previous method step of treatment delivery. Therefore, there is no image acquired at a time of treatment delivery.

Claim 37 is objected to because it is unclear what is meant by "objective function weights are learned." If this is claiming that a user may learn the objective function weights via experience, this would constitute non-statutory subject matter.

Claim 38 is objected to because it is unclear what is meant by the term "results."

Claim 39 is objected to because it is unclear how this relates to its parent claim. Specifically, it is unclear on to what the contours are generated.

Claims 55-57 are objected to because it is suggested that "from" be replaced with, for example, "derived from" or "acquired from" or "determined from."

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US Patent No. 5,117,829) – herein referred to as Miller – in view of Frohlich (US Patent Pub. No. 2002/0080915). Miller discloses patient alignment systems and procedures for radiation treatment. Figure 8 illustrates a flowchart of the procedure. As can be seen in this figure, a patient is first exposed to an imaging procedure within a pod. The pod is used to repeatedly reposition the patient for the treatment process and, therefore, when the patient is in the pod he or she is considered to be in a treatment

position. The patient is then transported within the pod to a treatment room and the table on which the patient and pod are attached is adjusted to settings determined by a treatment plan. Therefore, a treatment plan has already been created at this time. More images of the patient are acquired at this point in time. Corrections may be made, if they are required. If corrections are not required, treatment begins and adjustments may be made at any time once the treatment phase has begun. However, while it would be obvious to one of ordinary skill in the art that a treatment plan would include a dose distribution in radiation therapy, it is not explicitly stated within Miller that this is included within the treatment plan. Frohlich teaches a planning method and apparatus for radiotherapy treatment of a target volume in a body. The methods described by Frohlich "directly define the desired dose distribution instead of defining beam parameters. The desired dose distribution may be defined in different ways, e.g. by drawing on the two-dimensional (2D) CT slices (paragraph 6)." That paragraph also states that dose distribution may be determined via dose volume histograms (or DVH). Paragraph 11 describes the use of objective functions while paragraph 12 states that multiple treatment solutions are obtained. Paragraph 30-32 further describes multiple plan determination and benefits. Paragraph 25 teaches several imaging modalities that may be used to acquire images for the procedure. Therefore, it would be obvious to one of ordinary skill in the art that dose distributions may be determined via 2D images of a volume to be treated and it would be obvious to one of ordinary skill in the art to include a dose distribution plan in the treatment planning, as it is described and taught in Figure 8 of Miller, in order to later perform radiation therapy. Furthermore, the ability

of Frohlich to create multiple treatment plans would improve the methods of Miller by removing the need for "gathering new CT scan data and formulating a new treatment plan (column 15, lines 66-67)," thereby saving time and money.

Regarding new claims 28-31, the Examiner notes that these claims correspond to similar subject matter that was incorporated in now canceled claim 14. These features of the invention still read on the Miller reference as previously described and are rejected as such.

Regarding claims 33 and 35-39, these claims relate directly to original, now canceled claims 16-39, respectively. These claims are rejected over Miller as in the previous Office Action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

JMK